THE CLAIMS

What is claimed is:

1. A method of formulating a composition comprising one or more chemokines for use in a pharmaceutical composition having anti-HIV activity against one or more HIV-1 isolates present in an individual at a given time, the method comprising:

   (a) contacting a first aliquot of HIV^+ cells obtained from said individual with a chemokine, chemokine derivative and/or chemokine analog; and

   (b) comparing the ability to isolate HIV from said cells with the ability to isolate HIV from a second aliquot of HIV^+ cells obtained from said individual that are not contacted with said chemokines, chemokine derivatives and/or chemokine analogs;

   (c) formulating the composition to comprise one or more chemokines, chemokine derivatives and/or chemokine analogs, which produce a decrease in the ability to isolate virus in the presence of said chemokines, chemokine derivatives and/or chemokine analogs.

2. The method of claim 1, further comprising the step of combining in the composition two or more of said chemokines, chemokine derivatives and/or chemokine analogs demonstrating anti-viral activity against said HIV-1 isolates.

3. The method of claim 2 wherein at least 3 of said chemokines, chemokine derivatives and/or chemokine analogs are combined.

4. The method of claim 1 further comprising repeating said contacting and comparing steps for at least 2 individual chemokines, chemokine derivatives and/or chemokine analogs.

5. The method of claim 1 further comprising repeating said contacting and comparing steps for at least 3 individual chemokines, chemokine derivatives and/or chemokine analogs.

6. The method of claim 4 or 5 wherein the chemokines, derivatives, or analogs are selected from the group consisting of MCP-1, MCP-2, MCP-3, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin,

Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, and lymphotactin.

7. The method of claim 1 wherein the HIV^+ cells are co-cultured with uninfected $CD4^+$ peripheral blood mononuclear cells prior to said contacting with the chemokines, chemokine derivatives and/or chemokine analogs.

8. A method of formulating a pharmaceutical composition for a particular human subject infected with HIV, the method comprising:

(a) assaying a chemokine, chemokine derivative and/or chemokine analog for the ability to inhibit:

(i) HIV infection;

(ii) HIV replication; or

(iii) expression of an RNA or protein of HIV;

wherein said HIV is a primary isolate recovered from said subject; and

(b) combining an amount effective for therapy of a disease or disorder associated with HIV infection of one or more of said chemokines, chemokine derivatives and/or chemokine analogs demonstrating said ability with a pharmaceutically acceptable carrier suitable for use *in vivo* in humans.

9. The method of claim 9 wherein said assaying of the chemokine, derivative, or analog is by a method comprising:

(a) measuring HIV-1 levels in primary macrophage cells or primary $CD4^+$ peripheral blood mononuclear cells incubated with the primary isolate, which cells have been contacted with the chemokines, chemokine derivatives and/or chemokine analogs; and

(b) comparing the measured HIV-1 levels in the cells which have been contacted with the chemokines, chemokine derivatives and/or chemokine analogs with said levels in cells not so contacted with the chemokines, chemokine derivatives and/or chemokine

analogs, wherein a lower level in said contacted cells indicates that the chemokines, chemokine derivatives and/or chemokine analogs have anti-HIV activity.

10. The method of claim 9 wherein primary $CD4^+$ peripheral blood mononuclear cells are incubated with the primary isolate.

11. The method of claim 9 wherein the primary isolate has been propagated and maintained only in macrophages.

12. The method of claim 9 wherein the primary isolate is syncytia inducing.

13. The method of claim 9 wherein the primary isolate is non-syncytia inducing.

14. The method of claim 8 wherein said assaying of the chemokines, chemokine derivatives and/or chemokine analogs is by a method comprising:

(a) measuring HIV-1 levels in cultures of HIV^+ cells obtained from the patient which have been contacted with the chemokines, chemokine derivatives and/or chemokine analogs; and

(b) comparing said measured HIV-1 levels with said levels in said cells not so contacted with the chemokines, chemokine derivatives and/or chemokine analogs, wherein a lower HIV-1 level in cultures of said contacted cells indicates that the chemokines, chemokine derivatives and/or chemokine analogs has anti-HIV activity.

15. The method of claim 14 further comprising repeating steps (a) and (b) for at least 2 individual chemokines, or derivatives or analogs.

16. The method of claim 14 further comprising repeating steps (a) and (b) for at least 3 individual chemokines, or derivatives or analogs.

17. The method of claim 15 or 16 wherein the chemokines, derivatives, or analogs are selected from the group consisting of MCP-1, MCP-2, MCP-3, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, and lymphotactin.

18. A method of treating or preventing HIV infection or replication in a human subject in need of such treatment, the method comprising administering to the subject a pharmaceutical composition comprising:

(a) a chemokine selected from the group consisting of MCP-1, MCP-2, MCP-3, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, and lymphotactin in an amount effective to inhibit HIV infection or replication; and

(b) a pharmaceutically acceptable carrier.

19. The method of claim 18 wherein the only chemokines in said composition are those demonstrated to have activity against a primary HIV isolate from said subject.

20. The method of claim 18 wherein said pharmaceutical composition comprises at least 2 of said chemokines.

21. The method of claim 20 wherein the chemokines are selected from the group consisting of MCP-1, MCP-2, MCP-3, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, and lymphotactin.

22. A method of treating or preventing HIV infection or replication in a human subject in need of such treatment, the method comprising administering to the subject a pharmaceutical composition comprising:

(a) a nucleic acid encoding a chemokine selected from the group consisting of MCP-1, MCP-2, MCP-3, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, and lymphotactin, in an amount effective to inhibit HIV infection or replication; and

(b) a pharmaceutically acceptable carrier.

23. The method of claim 22 wherein said composition comprises nucleic acids encoding at least 2 of said chemokines.

24. The method of claim 23 wherein the nucleic acids encode chemokines selected from the group consisting of MCP-1, MCP-2, MCP-3, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, and lymphotactin.

25. A method of treating or preventing HIV infection or replication in a human subject in need of such treatment, the method comprising administering to the subject an amount of a purified protein effective to treat or prevent HIV infection, wherein the protein comprises a fragment or derivative of a chemokine selected from the group consisting of MCP-1, MCP-2, MCP-3, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, and lymphotactin.

26. The method of claim 25 wherein the only chemokine fragments or derivatives in said composition are those demonstrated to have activity against a primary HIV isolate from said subject.

27. The method of claim 25 wherein fragments or derivatives of at least 2 different chemokines are administered to the subject.

28. The method of claim 25 further comprising administering to the subject an anti-viral drug other than a chemokine, in an amount effective to inhibit HIV infection or replication.

29. The method of claim 28 wherein the other anti-viral drug is selected from one or more of the group consisting of AZT, ddI, ddC, 3TC, and sequinavir.

30. The method of claim 28 wherein the protein is administered intramuscularly.

31. A method of treating or preventing HIV infection or replication in a human subject, the method comprising administering to the subject wherein such treatment or prevention is desired an amount of a nucleic acid effective to treat or prevent HIV infection, wherein the nucleic acid encodes a fragment or derivative of a chemokine selected from the group consisting of MCP-1, MCP-2, MCP-3, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, and lymphotactin.

32. A method of treating or preventing HIV infection or replication in a human subjec, the method comprising administering to the subject wherein such treatment or prevention is desired a composition comprising:

(a) a first chemokine selected from the group consisting of RANTES, MIP-1α, MIP-1β, or IL-8;

(b) a second chemokine selected from the group consisting of MCP-1, MCP-2, MCP-3, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, lymphotactin, and SDF-1;

together in an amount effective to inhibit HIV infection or replication.

33. The method of claim 32 wherein the total of the chemokines selected from (a) and (b) is at least 3.

34. The method of claim 32 further comprising administering to the subject an anti-viral drug other than a chemokine, in an amount effective to inhibit HIV infection or replication.

35. The method of claim 34 wherein the anti-viral drug is selected from one or more of the group consisting of AZT, ddI, ddC, 3TC, and sequinavir.

36. The method of claim 32 wherein the composition is administered intramuscularly.

37. A method of treating or preventing HIV infection or replication in a human subject in need of such treatment, the method comprising administering to the subject a composition comprising:

(a) a first nucleic acid encoding RANTES, MIP-1α, MIP-1β, or IL-8, and

(b) a second nucleic acid encoding a chemokine selected from the group consisting of MCP-1, MCP-2, MCP-3, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, lymphotactin and SDF-1;

together in an amount effective to inhibit HIV infection or replication.

38. A pharmaceutical composition comprising:

(a) a chemokine selected from the group consisting of MCP-2, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, and lymphotactin, in an amount effective to inhibit HIV infection or replication; and

(b) a pharmaceutically acceptable carrier.

39. The pharmaceutical composition of claim 38 wherein the chemokine is purified.

40. The pharmaceutical composition of claim 38 further comprising at least 1, 2, 3, 4, 5, 6, 8, or 9 chemokines in an amount effective to inhibit HIV infection or replication.

41. The pharmaceutical composition of claim 38 further comprising RANTES, MIP-1α, MIP-1β, MCP-1, MCP-3, IL-8 or SDF-1 together in an amount effective to inhibit HIV infection or replication.

42. The pharmaceutical composition of claim 41 wherein the chemokines are purified.

43. A pharmaceutical composition comprising:

(a) a derivative or analog of a chemokine selected from the group consisting of MCP-2, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, and lymphotactin, in an amount effective to inhibit HIV infection or replication; and

(b) a pharmaceutically acceptable carrier.

44. The pharmaceutical composition of claim 43 wherein the chemokine derivative or analog is purified.

45. The pharmaceutical composition of claim 43 further comprising derivatives or analogs of at least 3 of said chemokines, in an amount effective to inhibit HIV infection or replication.

46. The pharmaceutical composition of claim 43 further comprising RANTES, MIP-1α, MIP-1β, MCP-1, MCP-3 or IL-8 in an amount effective to inhibit HIV infection or replication.

47. The pharmaceutical composition of claim 43 further comprising a derivative of RANTES, MIP-1α, MIP-1β, MCP-1, MCP-3 and IL-8 in an amount effective to inhibit HIV infection or replication.

48. A pharmaceutical composition comprising:

(a) one or more pharmaceutically active components selected from the group consisting of:

(i) a nucleic acid encoding a chemokine selected from the group consisting of MCP-2, MCP-4, MIP-1γ, MIP-3α, MIP-3β, eotaxin, Exodus, I-309, γIP-10, PF4, NAP-2, GRO-α, GRO-β, GRO-γ, ENA-78, GCP-2, lymphotactin and SDF-1, in an amount effective to inhibit HIV infection or replication; and

(ii) an analog of a chemokine of (i);

(iii) a fragment of a chemokine of (i);

(iv) a derivative of a chemokine, analog or fragment of (i), (ii), or (iii); and

(v) a nucleic acid encoding a chemokine chemokine, analog or fragment of (i), (ii), or (iii); and

(b) a pharmaceutically acceptable carrier.

49. A pharmaceutical composition comprising:

(a) two or more chemokines, each of which binds to at least one chemokine receptor selected from the group consisting of CC CKR-1, CC CKR-2A, CC CKR-2B, CC CKR-3, CC CKR-4, CC CKR-5, CxC CKR4, IL-8RA, IL-8RB, Mig receptor, γIP-10 receptor and Duffy antigen, in an amount effective to inhibit HIV infection or replication; and

(b) a pharmaceutically acceptable carrier.

50. A method of formulating a pharmaceutical composition having anti-HIV activity against one or more HIV-1 isolates present in an individual at a given time, the method comprising:

(a) contacting a first aliquot of $CD4^+$ cells, one or more virus isolates obtained from said individual, and a chemokine, chemokine derivative and/or chemokine analog; and

(b) comparing the ability to isolate HIV from said cells with the ability to isolate HIV from a second aliquot of $CD4^+$ cells contacted with said virus isolates that are not contacted with said chemokines, chemokine derivatives and/or chemokine analogs,

wherein a decrease in the ability to isolate virus in the presence of said chemokines, chemokine derivatives and/or chemokine analogs is indicative that the chemokines, chemokine derivatives and/or chemokine analogs has anti-viral activity against said HIV-1 isolates.

51. A pharmaceutical composition comprising MDC and I-309.

52. A method for treating HIV infection, the method comprising administering to a subject in need of such treatment a therapeutically effective amount of MDC and I-309.

53. The method of claim 52 wherein the MDC and I-309 are administered together as components of a pharmaceutical composition, along with a pharmaceutically acceptable carrier.

54. The method of claim 52 wherein the MDC and I-309 are administered in a synergistically effective and therapeutically effective amount.